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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/471,255	12/23/99	HAMEL	J 55190-012

HM11/0618

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EXAMINER	
PORTNER, V	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/471,255	Hamel et al
Examiner	**Art Unit**
Portner	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 23, 1999*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-31* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☒ Other: Sequence Letter

DETAILED ACTION

Claims 1-31 are pending.

Please note: Claim 30 is not being included in any of the groups, because claim 30 is drawn to a method, and depends from a composition claim. It is not clear what Applicant intended for claim 30 to recite. Claim 30 will be included in the group appropriate for the claim upon clarification of the invention.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-15, drawn to a plurality of independent and distinct isolated polynucleotide encoding a polypeptide, vectors, host cell and a process of using polynucleotide in a host cell, wherein each SEQ ID NO represents a separate invention, classified in class 536, subclass 23.7.

   II. Claims 16-20, 25 (in so far as the composition contains a bacterial polypeptide) drawn to a plurality of independent and distinct isolated bacterial polypeptides, wherein each SEQ ID NO represents a separate invention, classified in class 530, subclass 350.

   III. Claims 21-25 (in so far as the composition contains a bacterial chimeric polypeptide) drawn to a plurality of independent and distinct chimeric

polypeptides, wherein each combination of SEQ ID NOs represents a separate invention, classified in class 530, subclass 23.4.

IV. Claims 26-29 and 31 (in so far as the claims use a bacterial polypeptide), drawn to a plurality of independent and distinct methods of therapeutic or prophylactic treatment of disease using a bacterial polypeptide, wherein each SEQ ID NO represents a separate invention, classified in class 424, subclass 234.1.

V. Claims 26,28 and 31, 27 and 29 (in so far as the claims use a bacterial chimeric polypeptide), drawn to a plurality of independent and distinct methods of therapeutic or prophylactic treatment of disease using a chimeric bacterial polypeptide, wherein each combination of SEQ ID NOs represents a separate invention classified in class 424, subclass 192.1.

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the nucleic acid of Group I encodes a bacterial polypeptide product, while the polynucleotide of Group II, encodes an antibody, which they have different modes of operation, different functions, or different effects.

3. Inventions II and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, the chimeric polypeptide of Group III contains two polypeptides, while the Group II only contains a single polypeptide . The compositions of Group II and III differ structurally, and functionally from each other based upon the differences in amino acid structure. Inventions II and III have separate utility such as in methods of detecting different antibodies and stimulating different immune responses. See MPEP § 806.05(d).

4. Inventions IV and V are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention Group IV has separate utility such as stimulating an immune response to a single polypeptide while the chimeric polypeptide of Group V can be stimulate an immune response to two polypeptides, an immune response that the polypeptide of Group IV could not stimulate. The polypeptides used in the claimed methods also have separate utilities based upon the different structural and functional characteristics of each based upon differences in amino acid structure. See MPEP § 806.05(d).

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. Group I is drawn to a plurality of disclosed patentably distinct products comprising materially different polynucleotides (Group I: Nucleic acid molecules that encode SEQ ID NO 2,4,6,8, 10,14,16, 55 to 75, 77 to 79, 81 and 83 (claims 1-3), fragments, analogs and derivatives of SEQ ID Nos 2,4,6,8, 10,14,16, 55 to 75, 77 to 79, 81 and 83(claim 16-20), as well a complementary non-coding polynucleotides to SEQ ID NO 2,4,6,8, 10,14,16, 55-75, 77 to 79, 81 and 83 (claims 4-5)). Should the inventions of Group I be elected, Applicant would be required under 35 U.S.C. 121 to elect a single disclosed product, even though this requirement is traversed. The separate polynucleotides bear no structural or biochemical property in common and therefore each particular protein product claimed and would require a separate area of search and consideration tailored to the particular product under consideration.

7. Group II is drawn to to a plurality of disclosed patentably distinct products comprising materially different polypeptides (Group II: polypeptides of SEQ ID NO 2,4,6,8, 10,14,16, 55 to 75, 77 to 79, 81 and 83, fragments, analogs and derivatives of SEQ ID Nos 2,4,6,8, 10,14,16, 55 to 75, 77 to 79, 81 and 83(claim 18-20).) Should the inventions of Group II be elected, Applicant would be required under 35 U.S.C. 121 to elect a single disclosed product, even though this requirement is traversed. The separate polypeptides bear no structural or biochemical property in common and therefore each particular protein product claimed and would require a separate area of search and consideration tailored to the particular product under consideration.

8. Group III is drawn to to a plurality of disclosed patentably distinct products comprising materially different chimeric polynucleotides (Group III: Chimeric polypeptides that comprise two or more of SEQ ID NO 2,4,6,8, 10,14,16, 55 to 75, 77 to 79, 81 and 83, fragments, analogs and derivatives of SEQ ID Nos 2,4,6,8, 10,14,16, 55 to 75, 77 to 79, 81 and 83(claim 18-20). This group includes polypeptides that consist of 2 to 33 SEQ ID Nos, and polypeptides that are made up from fragments of any of the recited SEQ ID Nos. Specific species that contain 4 SEQ ID Nos are recited in claims 23 and 24.). Should the inventions of Group III be elected, Applicant would be required under 35 U.S.C. 121 to elect a single disclosed product, even though this requirement is traversed. The separate chimeric polynucleotides bear no structural or biochemical property in common and therefore each particular protein product claimed and would require a separate area of search and consideration tailored to the particular product under consideration.

9. Group IV is drawn to to a plurality of methods using disclosed patentably distinct products comprising materially different polypeptides (Group IV: Methods of treating or preventing infection using a single polypeptide of SEQ ID NO 2,4,6,8, 10,14,16, 55 to 75, 77 to 79, 81 and 83, or fragments, analogs and derivatives of SEQ ID Nos 2,4,6,8, 10,14,16, 55 to 75, 77 to 79, 81 and 83.). Should the inventions of Group IV be elected, Applicant would be required under 35 U.S.C. 121 to elect a single disclosed product, even though this requirement is traversed. The separate polypeptides bear no structural or biochemical property in common and therefore each

particular protein product claimed and would require a separate area of search and consideration tailored to the particular product under consideration.

10. Group V: is drawn to to a plurality of disclosed patentably distinct products comprising materially different chimeric polypeptides (Group V Methods of treating or preventing infection using a chimeric polypeptides that comprise two or more of SEQ ID NO 2,4,6,8, 10,14,16, 55 to 75, 77 to 79, 81 and 83, fragments, analogs and derivatives of SEQ ID Nos 2,4,6,8, 10,14,16, 55 to 75, 77 to 79, 81 and 83(claim 18-20). The methods administer chimeric polypeptides that consist of 2 to 33 SEQ ID Nos, and polypeptides that are made up from fragments of any of the recited SEQ ID Nos; specific species that contain 4 SEQ ID Nos are recited in claims 23 and 24..). Should the inventions of Group V be elected, Applicant would be required under 35 U.S.C. 121 to elect a single disclosed product, even though this requirement is traversed. The separate chimeric polypeptides bear no structural or biochemical property in common and therefore each particular protein product claimed and would require a separate area of search and consideration tailored to the particular product under consideration.

11. Should applicant traverse on the ground that the disclosed products are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either

instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp
June 6, 2001

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
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09/471,255	12/23/1999	Hamel et al	55190-012

EXAMINER	
Portner	
ART UNIT	PAPER NUMBER
1645	12

Please find below a communication from the EXAMINER in charge of this application

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

APPLICANT IS GIVEN 30 days FROM THE DATE OF THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.R.F. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Please Note: Figures 11 and 12 recite Sequences that do not show a SEQ ID NO in the Brief Description of the Drawings or in the figures. Assignment of SEQ ID Nos to the shown sequences is required for the Application to be in sequence compliance.

The response period for this letter is the same as the time period set for the Election/Restriction attached hereto.